

Docket: PP19768.002

DR

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Derek O'Hagan et al.
Application No.: 10/757,708
Date Filed: 01/14/2004
Title: MICROPARTICLES WITH ADSORBED POLYPEPTIDE-CONTAINING SPECIES
Group Art Unit: 1632
Examiner: Unassigned
Atty. Docket No.: PP19768.002

INFORMATION DISCLOSURE STATEMENT (IDS)

Mail Stop DD
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SIR:

In accordance with 37 C.F.R. §1.56 and in compliance with 37 C.F.R. §§1.97 and 1.98, the references listed on attached Form PTO/SB/08 and/or subsequently identified herein, are being submitted herewith for consideration by the United States Patent and Trademark Office.

I. COPIES

- a. ☒ A legible copy of (i) each foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed, is included herewith.
- b. ☐ Any patents, publications or other information which are listed on PTO/SB/08 which are not enclosed herewith were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. §120:

U.S. Serial Number

U.S. Filing Date

II. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

- a. ☒ Except as may be indicated below in (b) of this section, all of the patents, publications or other information are in the English language (concise explanation not required).
- b. ☐ A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows:
- c. ☐ The following additional information is provided for the Examiner's consideration:

III. ☐ CROSS REFERENCE TO RELATED APPLICATION(S)

The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this (these) applications to the Examiner's attention, Applicant(s) does(do) not waive the confidentiality provisions of 35 U.S.C. §122.

Serial No.

Filing Date

Art Unit

FEES

- IV. ☒ THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(b): (check one box)
- a. ☐ within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. §1.97(b)(1)). No fee or statement is required.
 - b. ☐ within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. §1.97(b)(2)). No fee or statement is required.
 - c. ☒ before the mailing date of a first Office Action on the merits (37 C.F.R. §1.97(b)(3)). No fee or statement is required.
 - d. ☐ before the mailing date of a first Office Action after the filing of a request for continued examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.
- V. ☐ THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(c): (check one box)
before the mailing date of any of a Final Office Action under 37 C.F.R. §1.113, a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application (See 37 C.F.R. §1.97(c)).
- a. ☐ No statement; therefore, charge deposit account 50-1047 the fee set forth in 37 C.F.R. §1.17(p).
 - b. ☐ See the statement below. No fee is required.
- VI. ☐ THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(d):
on or before payment of the issue fee and is accompanied by the following:
- 1) a statement under 37 C.F.R. §1.97(e) as provided below; and
 - 2) charge deposit account 50-1047 the petition fee set forth in §1.17(p).
- VII. ☐ STATEMENT UNDER 37 C.F.R. §1.97(e) (check only one box, if applicable)
The undersigned hereby states that
- a. ☐ each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of IDS; or
 - b. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and to knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement, or
 - c. ☐ some of the items of information contained in the IDS were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement.
- VIII. PAYMENT OF FEES
- ☐ A check in the amount of _____ is enclosed for the above-identified fee(s).
 - ☐ Please charge Deposit Account No. 50-1047 in the amount of \$180.00 for the above-indicated fee(s).
 - ☒ If Applicant has overlooked any additional fees, or if any overpayment has been made, the Commissioner is hereby authorized to credit or debit Deposit Account 50-1047.
 - ☐ Two Copies of this paper are attached for Deposit Account charges and debits.

It is Applicant(s)' opinion that the claims presently on file patently distinguish the present invention from each of these references. The above references are being cited only in the interests of candor and without any admission that they constitute statutory prior art or contain matter which anticipates the invention or which would render the same obvious, either singly or in a combination, to a person of ordinary skill in the art.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 50-1047.

Respectfully submitted,



Keum J. Park
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Enclosures: ☒ PTO/SB/08
☒ References; US patents omitted, as not required
☐ Foreign Search Report
☐ Other:

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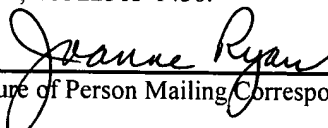
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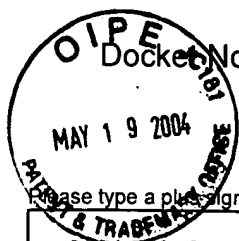
Substitute for form 1449A/PTO				<div style="text-align: center;">  </div>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	10/757,708
				Filing Date	01/14/2004
				First Named Inventor	Derek O'Hagan et al.
				Group Art Unit	1632
				Examiner Name	Unassigned
Sheet	1	of	2	Attorney Docket Number	PP19768.002

[illegible]

Examiner Initials*	Cite No. 1	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T
		Office ³	Number ⁴	Class/Subclass			
	1.	WO	02/26209 A2	A61K 9/00	Chiron Corporation	04/04/2002	
	2.	WO	00/50006	A61K 9/107	Chiron Corporation	08/31/2000	
	3.	WO	98/33487	A61K 9/16	Chiron Corporation	08/06/1998	
	4.	WO	03/028661 A2	A61K	Chiron Corporation	04/10/2003	
	5.	WO	00/06123	A61K 9/16	Chiron Corporation	02/10/2000	
	6.	WO	01/36599 A1	C12N 5/06	Chiron Corporation	05/25/2001	
	7.	WO	02/26212 A2	A61K 9/16	Chiron Corporation	04/04/2002	
	8.	WO	01/81609 A2	C12N 15/86	Chiron Corporation	11/01/2001	
	9.	WO	03/070909 A2	C12N	Chiron Corporation	08/28/2003	

Examiner Signature		Date Considered	
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¹ Unique citation designation number. ² See Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English Language Translation is attached.



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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 2

Complete if Known

Application Number	10/757,708
Filing Date	01/14/2004
First Named Inventor	Derek O'Hagan et al.
Group Art Unit	1632
Examiner Name	Unassigned
Attorney Docket Number	19768.002

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1.	M. Briones et al., "The Preparation, Characterization, and Evaluation of Cationic Microparticles for DNA Vaccine Therapy," <i>Pharmaceutical Research</i> , Vol. 18, no. 5, 2001, pp. 709-712.	
	2.	J. Kazzaz et al., "Novel Anionic Microparticles Are a Potent Adjuvant for the Induction of Cytotoxic T Lymphocytes Against Recombinant p55 Gag from HIV-1," <i>Journal of Controlled Release</i> , Vol. 67, 2000, pp. 347-356.	
	3.	K.S. Denis-Mize et al., "Plasmid DNA Adsorbed onto Cationic Microparticles Mediates Target Gene Expression and Antigen Presentation by Dendritic Cells," <i>GeneTherapy</i> , Vol. 7, 2000, pp. 2105-2112.	
	4.	Manmohan Singh et al., "Cationic Microparticles Are an Effective Delivery System for Immune Stimulatory CpG DNA," <i>Pharmaceutical Research</i> , Vol. 18, no. 10, October 2001, pp. 1476-1479.	
	5.	Manmohan Singh et al., "Cationic Microparticles: A Potent Delivery System for DNA Vaccines," <i>Proceedings of the National Academy of Science USA</i> , Vol. 97, no. 2, Jan. 18, 2000, pp. 811-816.	
	6.	Manmohan Singh et al., "Mucosal Immunization with HIV-1 Gag DNA on Cationic Microparticles Prolongs Gene Expression and Enhances Local and Systemic Immunity," <i>Vaccine</i> , Vol. 20, 2002, pp. 594-602.	
	7.	Derek O'Hagan et al., "Induction of Potent Immune Responses by Cationic Microparticles with Adsorbed Human Immunodeficiency Virus DNA Vaccines," <i>Journal of Virology</i> , Vol. 75, no. 19, Oct. 2001, pp. 9037-9043.	

Examiner Signature	Date Considered
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation, if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English Language Translation is attached.